Remarks

Claims 1-3 were pending in the subject application. By this amendment, Claims 1-3 have been amended to further clarify applicants' invention, and new Claims 24 -26 have been added. Support for new dependent Claim 24 can be found in the specification as originally filed at, *inter alia*, Table 1 and Table 2. Support for new dependent Claim 25 can be found in the specification as originally filed at, *inter alia*, page 13, lines 22-23. Support for new independent Claim 26, which is rewritten from the step recited in Claim 1, can be found in the specification as originally filed at, *inter alia*, page 7, lines 6 and 7, and page 12, lines 13 and 14. The specification also has been amended at page 1 to correct the information concerning governmental support. The amendments to the claims and specification do not introduce new matter. Accordingly, entry of the preceding amendments is respectfully requested.

Summary of February 16, 2011 Telephone Interview With Examiner

Applicants thank the Examiner for extending the courtesy of a telephonic interview with the undersigned on February 16, 2011. During the interview, the undersigned discussed certain claim language, in particular the characteristic recited in Claim 1 of "*may be* at risk for autism," that applicants believe support their position that the method as claimed is enabled.

Claims Rejected Under 35 U.S.C. §112, Enablement

Claims 1-3 were rejected in the January 18, 2011 Final Office Action as not enabled. The Final Office Action states, *inter alia*, that the method "requires the knowledge of a robust and reliable correlation [of the] association between the polymorphisms rs2056202 and rs2292813 and susceptibility to autism." The Final Office Action also comments on statements in the specification qualifying the observed experimental results, and states that such statements "demonstrate the need for

replication studies to validate the data." The Final Office Action also discusses published art, and states that the art "cautions in drawing conclusions from a single report of an association between a genetic variant and disease susceptibility."

In response, applicants respectfully traverse the enablement rejection. Applicants initially note that the claimed method is a "A method of evaluating whether a human may be at risk for autism," (emphasis added), with the conclusion of the claim reciting "the presence of a G at either or both of the two sites" indicates that the human "may be at risk for autism," (emphasis added). Notably, the method does not conclude with the absolute statement: "indicating that the human is at risk for autism." Thus, the Examiner's assertion that method "requires the knowledge of a robust and reliable correlation [of the] association between the polymorphisms rs2056202 and rs2292813 and susceptibility to autism" is simply incorrect. The "certainty" requirement imposed by the Examiner is not germane to the "may be at risk" characteristic of the method. In this respect, applicants note that the enablement requirement must be applied to the method *as claimed*. Insofar as the current enablement rejection apparently pertains to a *different* method, it is improper and should be withdrawn.

Applicants also note that the Examiner has characterized the specification as discussing further validation studies. However, further "validating" a discovery, (for example, in consideration of academic journal publication), is not an additional requirement for enablement. Instead, enablement requires asking does the disclosure "enable one skilled in the pertinent art to make and use the claimed invention," (MPEP §2164.01). In the present case, the specification sets forth how one skilled in the art can perform the claimed method. The steps of the method are straightforward to one skilled in the art: "comprising determining the human's genotype at polymorphism sites rs2056202 and/or rs2292813 of the SLC25A12 gene". There is no issue as to performing the steps of the method. Moreover, as stated above, the method is for "evaluating whether a human may be at risk for autism" (emphasis added). The data in the

specification supports that certain polymorphisms at sites rs2056202 and/or rs2292813 of the SLC25A12 gene are consistent with the subject being at risk of autism, as does a plurality of post-filing studies (Serguando et al., Turunen et al., and Silverman as previously disclosed to the Office by applicants). Thus, the conclusion draw from the presence of a G at either or both of the two sites, that the subject may be at risk, is described in, and supported by, the specification and is supported by post-filing art. Accordingly, it is not proper to maintain that the method as claimed is not enabled.

As to the Examiner's citation of additional post-filing art characterized as identifying that "the SLC25A12 gene is not associated with autism," the presence of multiple articles, some showing a link and some not showing a link, is not incompatible with, and is consistent with, the claimed method of "evaluating whether a human may be at risk for autism." Moreover, all the pertinent art should be considered, not just art showing a lack of association. Thus, while four results (the present disclosure, Serguando et al., Turunen et al., and Silverman) can be characterized as showing an association, and four other results (Chien et al., Corriera et al., Rabionet et al. and Blasi et al.) are characterized by the Examiner as not showing an association, such a distribution is consistent with "wherein the presence of a G at either or both of the two sites indicates the human *may be* at risk for autism." Thus, both the specification and the art support the assertion that the claimed method was enabled at the time of filing. One skilled in the art following the teachings of the disclosure would be able to evaluate whether a human subject may be at risk for autism.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

New Claims 24-26

New Claim 24, directed to the "method of claim 1, wherein the human has a G*G haplotype at the polymorphism sites," has been added herein to address the Examiner's concern that the haplotype G*A was not associated with parental transmission of autism.

New Claim 25, directed to the "method of claim 1, wherein the human does not have a rs105299 polymorphism," describes a particular population not explicitly discussed in the cited art.

New Claim 26 is directed to a method which applicants understand would not be subject to the current enablement rejection.

Conclusion

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the rejections set forth in the January 18, 2011 Final Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

The total fee amount of $650.00, including the $405.00 fee for filing an RCE and the $245.00 fee for a two-month extension of time for a small entity, is hereby authorized to be charged to Deposit Account No. 01-1785. No other fee is deemed necessary in connection with the submission of this reply and the accompanying RCE. However, if any other fee is required in connection with this submission or to maintain the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785.

Respectfully submitted,

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Dated: New York, New York
June 13, 2011

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